

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0472947	(X3) Date Survey Completed 07/24/2019
Name of Provider or Supplier Urology Center Of Southern Oklahoma, Pc	Street Address, City, State 1119 Walnut Dr, Ste 2, Ardmore, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The recertification survey was performed 07/24/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the practice manager and testing person #1 at the conclusion of the survey.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the office manager and testing person #1, the laboratory failed to have a written policy for verification of the accuracy of automated urinalysis testing. Findings include: (1) At the beginning of the survey, the office manager stated to the surveyor, the laboratory performed automated urinalysis testing using the Multistix PRO 10LS reagent dipsticks. In addition, the office manager stated the Clinitek Advantus dipstick reader (moderate complexity) was the primary instrument and the Clinitek Status dipstick reader (waived complexity) was the backup. Because dipstick urinalysis analytes (i.e., pH, glucose, ketones, specific gravity, blood, protein, nitrates, leukocyte esterase, and creatinine) are not regulated tests, twice per year accuracy verification is required; (2) The surveyor reviewed records from 09/01/17 through the day of the survey for accuracy verification of urinalysis testing performed on the Clinitek Advantus. The surveyor identified the laboratory performed twice per year accuracy of urinalysis testing by analyzing a "positive" and a "negative" patient sample on both the Clinitek Advantus and the Clinitek Status dipstick readers. The laboratory director then reviewed the results and determined if the comparison was acceptable; (3) The surveyor asked the office manager and testing person #1 how the results of the</p>

accuracy testing had been evaluated. Testing person #1 stated to the surveyor the laboratory director reviewed and compared the results and determined if the accuracy was acceptable; (4) The surveyor then reviewed the laboratory policy and procedure manual but could not locate a written policy and procedure for performing and evaluating the results of the twice per year accuracy verification of the urinalysis testing; (5) The surveyor then asked the office manager if the laboratory had a written policy and procedure for performing the twice per year accuracy verification of urinalysis testing, which would include guidance on the evaluation of results and determination of the acceptability of the results. The office manager and testing person #1 stated to the surveyor, the laboratory did not have a written policy and procedure which included criteria for determining acceptability of the accuracy verification.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with the office manager and testing person #1, the laboratory failed to ensure the manufacturer's environmental requirements were met. Findings include: (1) At the beginning of the survey, the office manager stated to the surveyor the laboratory performed urinalysis testing using the Clinitek Advantus dipstick reader and the Multistix PRO 10LS reagent dipsticks. In addition, testing person stated to the surveyor two levels of urinalysis QC (Quality Control) materials were tested each day of patient testing; (2) The surveyor reviewed the QC records for 2018 and 2019 and identified the laboratory used the following QC materials: (a) From 01/01/18 through 05/31/19, Level 1 and Level 2 of Avantamatrix Dipper Urinalysis Dipper Controls were used. The manufacturer required a storage temperature of 35.6-46.4 degrees F (Fahrenheit) (2-8 degrees Centigrade) (b) From 05/31/19 through the day of the survey, Level 1 and Level 2 of Consult Diagnostic Premium Liquid Urine Controls were used. (Level 1, Lot #150021 and Level 2, Lot #150022 were in use on the day of the survey). The manufacturer required a storage temperature of 35.6-46.4 degrees F (2-8 degrees Centigrade). (3) Testing person #1 stated to the surveyor the urinalysis QC materials were stored in the GE refrigerator located in the laboratory. The surveyor then reviewed the refrigerator temperature logs from 7 months (January, September, and December 2018; February, May, June, and through the day of the survey in July 2019) and identified on 12 of the 205 days reviewed, the refrigerator temperature was colder than the manufacturer's storage temperature. The findings follow: (a) May 2019: 4 of 19 days the temperature was too cold: (i) The temperature was 34.0 degrees F: Days 6,13,28,19 (b) June 2019: 4 of 18 days the temperature was too cold: (i) The temperature was 34.0 degrees F: Days 19,20,24,27 (c) July 2019: 4 of 14 days the temperature was too cold: (i) The temperature was 34.0 degrees F: Days 1,19,23,24 (4) The surveyor reviewed the findings with the office manager and testing person #1. The office manager and testing person #1 stated to the surveyor the

laboratory failed to ensure the urinalysis QC materials had been stored as required by the manufacturer, as listed above.